

REMARKS

Claim Objections

Errors to claims 3 and 16 resulting from scanning of prior claims have been corrected. Because these claims are being corrected to the original form and not being amended, the claim identifier lists these as original claims. Withdrawal of the rejection is requested.

Claim Amendments

Claim 1 has been amended to recite that the catheter balloon is prepared from a polymer material that has axial (i.e. longitudinal) orientation. This amendment is supported by the specification at, for example, page 17, lines 2-4 and page 32, lines 21-23 (paragraphs [0032] and [0082], respectively, of the published application). Claims 11, 13-19, 36, 38-41, 43 and 44 have been amended to refer to a shrunk catheter balloon and are supported throughout the specification. Claim 11 has been amended to recite that the shrunken catheter balloon has a wall thickness that is less than the tube from which it was formed and is supported by the specification at, for example, page 32, lines 1-28 (paragraph [0081] of the published application). Claim 12 is canceled without prejudice or disclaimer. Claim 39 has been amended to recite, *inter alia*, axially stretching a polymer tube and “heating the balloon while restraining axial contraction in a controlled manner.” These amendments are supported by the specification at, for example, page 16, line 26 through page 17, line 12 (paragraphs [0032]-[0034] of the published application).

Claim Rejections

The Applicant thanks the Examiner for the telephone discussions of the cited Crofts reference and claims on July 25 and 29, 2008.

In the Office Action, claims 1-21, 25 and 35-47 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,467,002 to Crofts. Applicant respectfully traverses. Although Applicant believes that the original claims are patentable over Crofts, solely to advance prosecution, independent claims 1, 11 and 39 have been amended to more clearly recite features that further describe features of the invention.

The method used to prepare the presently claimed invention and some of the resultant advantages were described in the prior response. That discussion is reiterated herein, but for the sake of brevity will not be repeated here.

As discussed during the phone call with the Examiner, Crofts teaches formation of a dimensionally recoverable polymeric article made by restraining axial movement of the article while radially **expanding** it. (see col. 4, lines 61-65) In contrast, the present claims are drawn to a catheter balloon formed by a method that includes restraining axial movement of an article while radially **shrinking** it. Crofts does not disclose restraining the article during the shrinking (or recovery) step. Crofts indicates that the disclosed method minimizes changes in length of the article during shrinking (see, col. 4, lines 50-53; col. 7 lines 15-16) Applicant understands that the Examiner's position is that this minimization of shrinkage reads on axially restraining, but disagrees. Crofts does not teach or suggest actively restraining the article during shrinking, but only passively allowing recovery with the possible result of little shrinkage. This is not structurally the same as the presently claimed invention.

Crofts discloses expanding a tubular article while holding the article. Thus, a tube with a certain length and wall thickness is expanded, which will necessarily result in a thinning of the walls in the expanded portion. As stated in Crofts, when this expanded article is then shrunk, it will return to approximately its original state. Importantly, the wall thickness in the recovered (shrunken) article will be about the same as the wall thickness of the original article.

In contrast, according to the present invention, a tubular polymeric article is expanded, usually with stretching, to provide an inflated catheter balloon portion. This expanded balloon is then shrunk while actively constraining the length. As a result, the shrunken catheter balloon has several features not found in Crofts as explained further below.

With respect to claim 1, as previously discussed, Crofts discloses axially restraining a balloon during the expansion step. Because of this axially restraint, the polymer material stretches radially, i.e. along the circumference of the expanded region, and the polymer material becomes oriented in this direction. The tube of Croft is

specifically not stretched in the axial (longitudinal) direction when expanded but rather Croft specifically recites that it is prevented from stretching longitudinally when expanded which eliminates any tendency to axially change when the object is eventually shrunk. As a result, no orientation is imparted in the axial direction. Since there is no axial change when shrunk, no orientation is imparted in that step as well. Accordingly Croft does not provide a catheter balloon with axial orientation and can not anticipate claim 1 of the present application.

Similarly, with respect to claim 39, the product produced by the recited process is different from Croft. Claim 39 now recites stretching the tube and restraining axial contraction during shrinkage, a method distinctly different from the method of Crofts. Because of these differences in the method of forming the balloon, the product is different from that of Croft and claim 39 can not be anticipated.

Claim 11 has been amended to recite that a wall thickness of the balloon is less than the wall thickness of tube from which it was formed. (see for example page 32, lines 1-28) Applicants note that a catheter balloon might include cuffs at the ends during its formation that are formed from the tube from which the balloon is blown (see, for example, FIG. 1B and elements 17 and 19 of FIG. 1C) The wall thickness of the balloon is thus less than the wall thickness of the cuffs and the rest of the tube from which the balloon was formed. This feature would not be present in the shrunk article of Crofts. Further, as described elsewhere herein, even if the cuffs are removed, the resultant balloon has properties that are different than Crofts.

Because of the physical differences between the present invention and Crofts, there is a difference in properties between the article of Crofts and the presently claimed catheter balloon with respect to the propensity for re-expansion after contraction. In Crofts, once the article is recovered, it essentially returns to its initial state. There is no more tendency for the article to expand when pressurized than was the initial tube or article from which it is formed. In order to re-expand the article, the same steps must be taken as were taken to initially expand the article. In contrast, a shrunk catheter balloon according to the present invention will, when pressurized, tend to return to its expanded state, and in fact needs to do so in order to function as a catheter balloon. Applicant notes

that the article disclosed in Crofts is not a catheter balloon and there is no need for re-expansion. This is a structural differences distinguishing Crofts from the present invention. These differences in properties are a result of the differences between the method of Crofts and the present invention, and the structural differences that result from the different methods. Accordingly, the article disclosed by Crofts is inherently different from the presently claimed article.

Stated differently, the catheter balloon intermediate of the present invention, as well as the final product, will change dimensions perpendicular to the expansion direction when reheated unless axial restraint is applied, since the shrink memory is imparted by stretching axially and radially when the balloon is formed. Thus, the axial stretch memory remains after shrinking the balloon intermediate due to the application of “axial restraint”. Holding the tubing ends while heat shrinking maintains the axial orientation of the balloon intermediate into the final product. These features are not disclosed, suggested or taught by Crofts.

For the reasons stated above, Applicant respectfully submits that Crofts does not teach, disclose or suggest the presently claimed invention. Accordingly, the rejections should be withdrawn.

Claims 22 and 24 were rejected under 35 U.S.C. § 103 as obvious over Crofts in view of U.S. Patent No. 4,275,180 to Clarke. Claims 22 and 24 have been canceled, rendering the rejection moot.

Conclusion

All of the stated grounds of objection and rejection are believed to have been properly overcome, traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. An early notice indicating the allowability of claims 1-11, 13-19, and 35-48 is respectfully requested.

The Examiner is respectfully requested to contact Applicant's undersigned Representative if necessary to place the application in condition for allowance.

Respectfully submitted,

DRAFT

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